IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 99-499)

In the Application of:	)	
	)	
Chou et al.	)	**Examiner: D. Fox**
	)	
Serial No.: 08/903,944	)	**Group Art Unit: 1638**
	)	
Filing Date: July 31, 1997	)	**Confirmation No.: 3007**
	)	
For: Production of Transgenic Poinsettia	)	

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The applicants hereby file an original and three copies of this appeal brief.

I. REAL PARTY IN INTEREST

The real party in interest is The Scotts Company of Marysville, Ohio.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

III. STATUS OF CLAIMS

Upon filing of this appeal and entry of the applicants' second after final response, mailed April 7, 2004:

claims 1-72, 97-99, 101-111, and 113-188 are canceled; and

claims 73-96, 100, and 112 are pending and rejected, which rejections are appealed from.

A clean set of the claims as pending upon entry of the second after final response is attached as Appendix A.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed January 30, 2004 stated that the amendments in the applicants' first after final response, filed December 29, 2003, would not be entered without additional examiner's amendments. As reflected in the Interview Summary mailed with the Advisory Action, the applicants declined to accept the suggested amendments.

The applicants have not yet been informed by the Office whether the amendments filed in the second after final response have been entered.

V. SUMMARY OF THE INVENTION

The presently claimed invention comprises transgenic poinsettia plants. Poinsettia plants are the primary potted flowering plant produced and sold in North America. P. 1, lns. 23-25. Accordingly, improved poinsettia are desirable and provided by the presently claimed invention.

Poinsettia, like many plants, are susceptible to a number of insect pests and diseases, even under greenhouse conditions. P. 2, lns. 5-6. While chemical treatment can control certain pests and disease-causing pathogens, they can also have deleterious effects on the plants. P. 2, lns. 25-27. An alternative to chemical treatment is to genetically engineer poinsettia that express polypeptides capable of protecting the plant against insects and pathogens as well as to enhance the commercial value of the poinsettia by controlling various commercially valuable phenotypes. P. 2, lns. 27-36. Until the filing of the present application, no transgenic poinsettia have been produced. P. 3, lns. 1-2.

The present claims provide for the first time transgenic poinsettia plants. P. 3, lns. 7-21, p. 9, lns. 31-33.

VI. ISSUES

The issues presented to the Board after entry of the second after final amendment are the following:

A. Whether claims 73–96, 100, and 112 are enabled under 35 U.S.C. § 112, first paragraph.

B. Whether claims 73-75, 83, and 85 are adequately supported by the specification under the written description requirement of 35 U.S.C. § 112, first paragraph.

VII. GROUPING OF THE CLAIMS

A. With regard to the enablement rejection under 35 U.S.C. § 112, first paragraph, all the claims rejected for this reason stand or fall together (*i.e.*, claims 73–96, 100, and 112).

B. With regard to the written description rejection under 35 U.S.C. § 112, first paragraph, all the claims rejected for this reason stand or fall together (*i.e.*, claims 73-75, 83, and 85).

VIII. ARGUMENT

A. Enablement rejection under 35 U.S.C. § 112, first paragraph

Claims 73–96, 100, and 112 stand rejected because, according to the Examiner, "the specification, while being enabling for claims limited to a method of producing transgenic poinsettia utilizing particle bombardment of embryogenic callus and the resultant plants produced by such a method, does not reasonably provide enablement for claims broadly drawn to transgenic poinsettia plants produced by any method. . . . The specification only provides guidance for the production of whole, flowering poinsettia plants produced by particle bombardment of embryogenic callus." Office Action Mailed 7/30/2002 (paper no. 86), p. 3. This rejection has been maintained through the most recent Office Action. *See* Final Office Action Mailed 9/26/03 (paper no. 41), p. 2. The applicants respectfully traverse.

The pending claims are drawn to transgenic plants and not a method of producing transgenic plants. All that § 112 requires with regard to enablement is the disclosure of a single method by which one of ordinary skill in the art can make and use the claimed plants without undue experimentation. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003) ("the law makes clear that the specification need teach only one mode of making and using a claimed composition"); *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) ("the enablement requirement is met if the description enables any mode of making and using the invention") (quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)); *see also Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1308 (Fed. Cir. 2001). The Examiner has acknowledged that the specification is enabling for claims to transgenic poinsettia plants produced by microprojectile-mediated transformation. *See* Final Office Action Mailed 9/26/03 (paper no. 41), p. 2. Whether the specification also discloses the production of transgenic poinsettia by Agrobacterium-mediated transformation or by any other method is irrelevant to the issue of whether the presently pending transgenic plant claims are enabled.

In view of the foregoing, the applicants respectfully request reversal of the enablement rejection.

B. Written description rejection under 35 U.S.C. § 112, first paragraph.

Claims 73-75, 83, and 85 stand rejected under the written description requirement of 35 U.S.C. § 112, first paragraph because, according to the Examiner, "[t]he claims are broadly drawn to any transgenic poinsettia plant which contains any heterologous coding sequence conferring any trait. No guidance has been provided for a multitude of coding sequences conferring a multitude of traits. Only specific coding sequences conferring disease or insect resistance, herbicide resistance, modified plant habit, ethylene resistance, antibiotic resistance, early flowering, and delayed senescence were provided . . . ." Office Action Mailed 7/30/2002 (paper no. 86), pp. 5-6. The Examiner relied on *University of California v. Eli Lilly and Co.* for the propositions that (1) to satisfy the written description requirement, one must provide a precise definition of the claimed subject matter to distinguish it from other materials, (2) naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material, and (3) to claim a genus the patentee must provide a representative number of species of the claimed genus so that one skilled in the art could visualize or recognize the identity of the members of the genus. *Id.* at p. 6. This rejection has been maintained through the most recent Office Action. *See* Final Office Action Mailed 9/26/03 (paper no. 41), p. 2. The applicants respectfully traverse.

The applicants respectfully submit that the Examiner has misapplied the law on written description and the Federal Circuit's holding in *Eli Lilly*. In *Eli Lilly*, the Federal Circuit considered whether a claim to a genus of newly discovered nucleic acid sequences encoding a protein having a known function satisfied the written description requirement when only a small handful of sequences within the genus were disclosed. The court held that in such instances defining physical characteristics of the claimed sequences were required; merely reciting the function of the sequence was insufficient. In *Enzo Biochem, Inc., v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002), the Federal Circuit clarified its *Eli Lilly* holding by stating that reciting a function may be sufficient to meet the written description requirements if there is a known correlation of function to a particular, known structure. Importantly, in *Eli Lilly* and *Enzo Biochem* the Federal Circuit was considering the nature of the written description required for new and previously unknown biological materials (*i.e.*, particular nucleic acids).

More recently, in a decision more apt to the present claims, the Federal Circuit considered whether claims to EPO produced by vertebrate (particularly mammalian) cells and processes for producing the EPO from those cells satisfied the written description requirement. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003). The defendant argued that the plaintiff, Amgen, failed to provide written description support for the terms "vertebrate cells" and "mammalian cells" recited in the EPO composition claims and the method claims. In rejecting the defendants' challenge, the Court stated:

> Both *Eli Lilly* and *Enzo Biochem* are inapposite to this case because the claim terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend. Instead, the claims of Amgen's patents refer to types of cells that can be used to produce recombinant human EPO. Thus, TKT [a defendant] can only challenge the adequacy of disclosure of the vertebrate or mammalian host cell – not the human DNA itself. This difference alone sufficiently distinguishes Eli Lilly, because when used, as here, merely to identify types of cells (instead of undescribed, previously unknown DNA sequences), the words "vertebrate" and "mammalian" readily "convey[] distinguishing information concerning [their] identity" such that one of ordinary skill in the art could "visualize or recognize the identity of the members of the genus." *Eli Lilly, 119 F.3d at 1567, 1568.*

Amgen, 314 F.3d at 1332.

As in *Amgen*, the terms objected to in the presently rejected claims do not describe previously unknown biological materials that ordinarily skilled artisans would easily miscomprehend. Rather, the terms convey distinguishing information concerning their identity such that one of ordinary skill in the art could visualize or recognize their identity. The term "foreign gene" clearly identifies to the ordinary artisan a gene that is not a poinsettia gene.

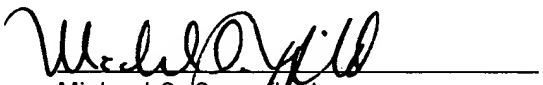
It is not incumbent on the applicants to describe all non-poinsettia (*i.e.*, foreign) genes. Those genes are not the applicants' claimed invention. Rather, the claims are drawn to transformed poinsettia plants, and the specification must supply adequate written description of the plants such that one skilled in the art could envision the claimed plants and understand that the applicants had possession of them. Just as the Federal Circuit held in *Amgen* that the terms "mammalian cells" and "vertebrate cells" are well known and therefore not new or unknown biological materials that the ordinary skilled artisan would easily misapprehend, "foreign genes" does not describe new or unknown biological materials that the ordinary skilled artisan would easily misapprehend – one skilled in the art can easily

apprehend non-poinsettia genes. The applicants respectfully submit that based on the present specification, one of ordinary skill in the art would have no difficulty (a) envisioning a poinsettia plant transformed with a foreign gene, and (b) understanding that the applicants, who for the first time demonstrated success in obtaining whole transformed poinsettia plants, contemplated and had possession of such transformed plants.

In view of the foregoing, the applicants respectfully request reversal of the written description rejection.

Respectfully submitted,

Date: April 26, 2004



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APPENDIX A

73. A transgenic poinsettia plant comprising at least one expression vector, wherein said expression vector comprises at least one foreign gene, and wherein said transgenic poinsettia plant expresses said foreign gene.

74. The transgenic poinsettia plant of claim 73, wherein said expression vector further comprises a promoter, wherein said promoter is selected from the group consisting of Cauliflower Mosaic Virus (CaMV) 35S promoter, the enhanced 35S promoter, the UBQ3 promoter, the UBQ10 promoter, the UBQ11 promoter, the UBQ14 promoter, the TEFA 1 promoter, the rolC promoter, and the Commelina Yellow Mottle Virus promoter, wherein the expression of said foreign gene is under the control of said promoter.

75. The transgenic poinsettia plant of claim 74, wherein said promoter is selected from the group consisting of the CaMV 35S promoter, the enhanced 35S promoter, the UBQ3 promoter, and the UBQ10 promoter.

76. The transgenic poinsettia plant of claim 73, wherein the expression of said foreign gene confers resistance to disease caused by an organism selected from the group consisting of virus, bacterium, and fungus.

77. The transgenic poinsettia plant of claim 76, wherein said foreign gene disrupts the function of said virus, and wherein said virus-disrupting gene is selected from the group consisting of genes encoding viral coat protein, 2′-5′ oligonucleotide synthetase, viral genome antisense RNA, and pokeweed B81antiviral protein.

78. The transgenic poinsettia plant of claim 73, wherein said foreign gene confers resistance to an insect, and wherein said insect resistance gene encodes a protein selected from the group consisting of tryptophan decarboxylase, lectin, and Bacillus thuringiensis toxin.

79. The transgenic poinsettia plant of claim 78 wherein said lectin is Galanthus nivalis lectin.

80. The transgenic poinsettia plant of claim 76, wherein said foreign gene confers resistance to a bacterium or a fungus and encodes a polypeptide selected from the group consisting of chitinase, a β-1,3-glucanase, ribosome-inactivating protein, lytic peptide, and plant defensin.

81. The transgenic poinsettia plant of claim 80, wherein said plant defensin is radish seed Rs-AFP2.

82. The transgenic poinsettia plant of claim 80, wherein said lytic peptide is selected from the group consisting of a magainin, PGLa, PGL, xenopsin, caerulein, cecropin, MSI-99, MSI-55, and D5-C.

83. The transgenic poinsettia plant of claim 73, wherein said foreign gene is operatively linked with a DNA molecule encoding pea vicilin signal peptide.

84. The transgenic poinsettia plant of claim 82, wherein said magainin in magainin 1 or magainin 2.

85. The transgenic poinsettia plant of claim 73, wherein said transgenic poinsettia comprises an expression vector that further comprises a second foreign gene.

86. The transgenic poinsettia plant of claim 85, wherein said foreign gene encodes chitinase, and wherein said second foreign gene encodes β-1,3-glucanase.

87. The transgenic poinsettia plant of claim 86, wherein said foreign gene encodes magainin 2, and wherein said second foreign gene encodes PGLa or PGL.

88. The transgenic poinsettia plant of claim 86, wherein the expression of said foreign gene confers insensitivity to ethylene, and wherein said foreign gene encodes a mutated ethylene receptor.

89. The transgenic poinsettia plant of claim 88, wherein said mutated ethylene receptor gene is the Arabidopsis etr-1 gene or a tomato NR gene.

90. The transgenic poinsettia plant of claim 73, wherein said foreign gene is the Vitreoscilla hemoglobin gene.

91. The transgenic poinsettia plant of claim 73, wherein said foreign gene is an isopentyenyl transferase gene, wherein the expression of said isopentynyl transferase gene is under the control of a promoter of a senescence-associated gene.

92. The transgenic poinsettia plant of claim 91, wherein said promoter is the Arabidopsis SAG12 gene promoter.

93. The transgenic poinsettia plant of claim 73, wherein said foreign gene encodes a polypeptide having a MADS box domain.

94. The transgenic poinsettia plant of claim 93, wherein said second foreign gene is selected from the group consisting of the PLENA gene, the SQUAMOSA gene, the DEFICIENS A gene, the GLOBOSA gene, the APTELA1 gene, the APETALA2 gene, the AGAMOUS gene, the Os-MADS24 gene, the OsMADS45 gene, and the OsMADS1 gene.

95. The transgenic poinsettia plant of claim 73, wherein said foreign gene encodes a protein that modifies plant habit.

96. The transgenic poinsettia plant of claim 95, wherein said gene is the OsMADS1 or phyA gene.

100. The transgenic poinsettia plant of claim 73, wherein said plant is fertile.

112. The transgenic poinsettia plant of claim 73, wherein the expression of said second foreign gene confers resistance to an insect.